DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 2, 2015

Ambient Clinical Analytics
% Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K143372
Trade/Device Name: Aware
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II
Product Code: MWI
Dated: January 19, 2015
Received: January 20, 2015

Dear Mark Job,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

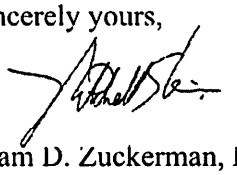
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143372

Device Name
AWARE™

Indications for Use *(Describe)*
AWARE™ is intended for use in the data collection, presentation, management and storage of patient information, and is used in conjunction with independent patient bedside devices and Hospital Information Systems connected via a network. This device is indicated for use by health care providers when providing patient care in an ICU and Emergency Department healthcare setting.

AWARE is indicated for use in the clinical care of hospitalized adult and pediatric patient (newborn, infant, child, and adolescent) with or at risk of critical illness.

AWARE is not an Electronic Medical Record (EMR) application and AWARE use is not intended to replace electronic data management systems utilized by healthcare institutions such as an EMR, LIMS (Laboratory Information Management System), PACS (Picture Archive Communication), patient medical device monitoring and alarm systems.

AWARE is not a medical Alarm System and AWARE use is not intended to replace medical Alarm Systems (including monitors) within a healthcare institution. AWARE provides no auditory alerts nor does it provide monitoring and alerting of life threatening situations such as a ventilator disconnection, asystolia, or arrhythmia. AWARE provides a visual ICU-based status of events reported from the institutions' source systems to aid in the clinical care decision process.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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AMBIENT
CLINICAL ANALYTICS

K143372

510(k) Summary
AWARE™ 1.0

1. Date Prepared: 2015-03-24

2. Owner:

Allen Berning
Ambient Clinical Analytics
221 1st Avenue SW
Rochester, MN 55902
United States
Phone: 952-240-6775
Email: info@ambientclinical.com

3. Contact person:

Amy Fowler
DuVal & Associates, P.A.
825 Nicollet Mall, Suite 1820
Minneapolis, MN 55402
United States
Phone: 612-338-7170, ext. 4
Email: fowler@duvalfdalaw.com

4. Trade name: AWARE™ Version 1.0

   Common/Usual Name is: Clinical Decision Support Software

   Classification Name: Cardiac monitor (including cardiotachometer and rate alarm) Monitor, Physiological, Patient (Without Arrhythmia Detection or Alarms)

   Product code: MWI

5. Predicate devices:
   a. MetaVision Graphical Patient Information System, iMDsoft, Ltd. Cleared for marketing as K012349 on January 29th, 2002, Product Code MWI.
   b. Intellivue Clinical Information Portfolio (ICIP), Philips Medical Systems. Cleared for marketing as K100272 on April 14th, 2010, Product Codes DXJ, NSX.

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6. Device Description:

AWARE ™ is a stand-alone software product used by professional care providers in ICU and Emergency Department healthcare settings for the presentation, collection, management and storage of patient information. The AWARE application was created based on healthcare provider requirements to provide patient data through the use of an interface with built-in tools, practice surveillance, and decision support. The philosophy behind the system is the following:

- Identify and present relevant information from an institution's currently deployed patient information systems
- Bundle related data into discrete systemic organ based packages to facilitate efficient informed decision making in a healthcare setting.
- Automatically collect and display critical patient data

7. Intended Use/Indications for Use:

AWARE™ is intended for use in the data collection, presentation, management and storage of patient information, and is used in conjunction with independent patient bedside devices and Hospital Information Systems connected via a network. This device is indicated for use by health care providers when providing patient care in an ICU and Emergency Department healthcare setting.

AWARE is indicated for use in the clinical care of hospitalized adult and pediatric patient (newborn, infant, child, and adolescent) with or at risk of critical illness.

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8. Summary of Technological Characteristics of AWARE™ compared to predicate devices:

The technological characteristics of AWARE™ and the predicate devices are the same. All devices use Microsoft SQL, existing IT infrastructure, and rules engine technology. All employ software and computers to interact with a healthcare institution's source electronic data systems via a network to collect, display, manage and store patient data. The way the system is used for generating patient records, computation of drug and fluid dosage and research tasks is determined by the health care providers, in terms of their environment and requirements.

The predicate application is resident on a workstation that provides for data input and patient data display to health care professionals. Typically, the predicate system comprises several workstations connected via a network system to one or more servers. Data is stored and managed by servers. The predicate system network can communicate with a number of remotely located patient care units.

The predicate applications "look and feel" is similar to Electronic Medical Records presentation of data, AWARE™ has a user interface designed from clinician requirements and that provide physiological systemic organ based views. The predicate applications perform patient admit and discharge functions and associated data input screens for billing, AWARE™ doesn't perform patient admit and discharge functions. The iMD system provides Research analytics and reporting, AWARE™ does not support Research analytics and reporting. The predicate Graphical Patient Information Systems supports 15 languages, AWARE™ supports English.

9. Non-clinical Performance:

Testing involved system level tests, performance tests and safety testing based on hazard analysis. Cybersecurity issues have been addressed. In addition to the verification and validation testing activities executed by Ambient Clinical Analytics to establish the performance and functionality of AWARE™ and the predicate devices, several standards were utilized:

14971	Medical Devices – Applications Of Risk Management To Medical Devices
62304	Medical Device Software – Software Life Cycle Processes
60601-1-8	Medical Electrical Equipment – Part 1-8: General Requirements For Basic Safety and Essential Performance – Collateral Standard: General Requirements, Tests and Guidance For Alarm Systems In Medical Electrical Equipment And Medical Electrical Systems

Usability testing was independently conducted and published:

Pickering BW, Herasevich V, Ahmed A, Gajic O. Novel Representation of Clinical Information in the ICU: Developing User Interfaces which Reduce Information Overload. Appl Clin Inform. 2010;1(2):116–31. doi:10.4338/ACI-2009-12-CR-0027. PMID: 23616831

Ahmed A, Chandra S, Herasevich V, Gajic O, Pickering BW. The effect of two different electronic health record user interfaces on intensive care provider task load, errors of cognition, and performance. Crit Care Med. 2011;39(7):1626–34. doi:10.1097/CCM.0b013e31821858a0. PMID: 21478739

JM Litell, TW Suther, CJ Ridgeway, IC Tiong, BW Pickering, V. Herasevich Representation of Organ System Domains in a Novel Critical Care EMR Interface: Implications for Effective Partnership Between Clinicians and Design Professionals. AMIA 2012 proceedings.

Marc D, Pickering B, Harder K, Herasevich V. Interpretation of graphical icons in a critical care EMR interface. AMIA 2013 proceedings.

Marc D, Thongprayoon C, et al. Two interfaces cognitive load efficiency user sat Comparing Accuracy, Efficiency, and User satisfaction of Two EMR. AMIA 2014 proceedings.

10. Clinical Performance:

    Not applicable.

11. Conclusions from Non-clinical Performance Testing:

    The AWARE™ 510(k) package and results on non-clinical testing demonstrate AWARE™ is substantially equivalent to the predicate devices, the iMDsoft MetaVision Graphical Patient Information System and the Philips Intellivue Clinical Information Portfolio.